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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
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DATE MAILED: *92*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No
09/076,404

Applicant(s)

Ecker et al.

Examiner
Ardin Marschel

Group Art Unit
1631



X Responsive to communication(s) filed on Jan 5, 2001

X This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11, 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133) Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- X Claim(s) 1-5 and 17-31 is/are pending in the application
~~or, if necessary, Claim(s) 6-16 have been canceled~~ ~~(One with election consideration)~~
 Claim(s) is/are allowed
 X Claim(s) 1-5 and 17-31 is/are rejected
 Claim(s) is/are objected to
 Claims are subject to restriction or election requirement

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
 The drawing(s) filed on is/are objected to by the Examiner.
 The proposed drawing correction, filed on is ☐ approved ☐ disapproved.
 The specification is objected to by the Examiner.
 The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d)
☐ All ☐ Some ☐ None of the CERTIFIED copies of the priority documents have been received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892
 Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
 Interview Summary, PTO-413
 Notice of Draftsperson's Patent Drawing Review, PTO-948
 Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Applicants' arguments, filed 1/5/01, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The amendment, filed 1/5/01, is objected to under 35 U.S.C. § 132 because it introduces NEW MATTER into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The insertion to the specification on page 94, lines 29-31, directed to software package names is NEW MATTER. The previous page 94, lines 29-31, citation only referenced companies by name and with the non-specific phrase "Software packages from companies...". Nowhere as filed was there written description, or even acknowledgement, of any particular or specific software packages. Presumably, these companies supply numerous software packages. Thus, how does the citation of a company name, as filed, indicate what product, such as software, is meant thereby? It is additionally noted that page 94, lines 28-29, indicate that the commercially available software is directed to designed molecules, chemistry, and available reaction building blocks. Nothing is stated therein that the software performs docking of

molecules such as in the DOCK program, discussed in the previous office action. Thus, there is also no written support to choose particular software packages from these commercial sources that "dock" molecules or define "molecular interaction sites" as required in the practice of the instant claims. It is noted that a Declaration has been filed from Dr. David Ecker. This Declaration indicates software packages but does not remedy the failure of applicants to provide such indication as filed. Additionally, the Declaration fails to indicate any function to the software that would be needed for the practice of the instant invention.

Applicant is required to cancel the new matter in the response to this Office action.

Claims 1-5 and 17-31 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the application of the program DOCK for modeling the interactions of molecules with a macromolecule's binding site, does not reasonably provide enablement for generally discovering the binding site(s) in macromolecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex

parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1998). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

This rejection is reiterated from the previous office action, mailed 10/11/00, and as necessitated by amendment regarding newly submitted claim 31. Applicants argue that they have amended into the specification the names of software packages for modeling in the specification on page 94, lines 29-31. This is non-persuasive because, as stated in the previous office action, mailed 10/11/00, these appear to be directed to essential subject matter for generic or broad claim practice and, as such, cannot provide enablement via incorporation by reference. Again, see the below given paragraph directed to the

incorporation of essential subject matter by reference. Another concern is in a common phrase given as "What's in a name"? It is clearly non-enabling to set forth a "name" without explanation of at least the capabilities of the software. Note also the above NEW MATTER rejection regarding these software packages.

The incorporation of essential material by reference to a foreign application or foreign patent or to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or applicant's attorney or agent, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157; *In re Hawkins*, 486 F.2d 579, 179 USPQ 163; *In re Hawkins*, 486 F.2d 577, 179 USPQ 167.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 17, 18, and 21-23 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Chen et al. (Biochemistry 30:11402[1997]):

This rejection is reiterated from the previous office action, mailed 10/11/00. Applicants firstly argue that the Chen et al. reference does not teach a molecular interaction site in a

target RNA. This is non-persuasive in that the previous office action, mailed 10/11/00, pointed to the analysis of 400 molecules, clearly a virtual library of compounds, in silico in a 3-D computer evaluation. Thus, this allegation of applicants is clearly contrary to the factual basis for this rejection and thus non-persuasive. Applicants then argue that the instant molecular interaction site is small usually less than 30 nucleotides and then confusingly admits that the Chen et al. reference is focused on a 4-9 base pair region which is apparently composed of 8-18 nucleotides which falls clearly within applicants' argued definition of the size of the "molecular interaction site" of the instant claims. This argument therefore is non-persuasive. Applicants further argue that the Chen et al. site is not independently folded or a functional subdomain of the target RNA molecule. It is well known that a major groove in RNA is only possible if base pairing has occurred in that region for the formation of such a groove. Thus, the 4-9 base pairs as argued by applicants clearly must have this characteristic and thus be independently folded as no major groove would occur in this RNA if the a central set of 4-9 bases did not base pair into hybridized form. Thus, this independent folding characteristic of this region clearly qualifies it as independently folded. The functional subdomain limitation is also met by this region in that the "binding function" in this region is well documented by

the modeling already discussed above. Applicants further argue that the central base pairing region of the noted RNA in Chen et al. is not independently folded due to be part of a larger RNA. In response, it is noted that nucleic acid folding such as RNA is well known in the art to require the consideration of at least some contribution regarding folding from all parts of such a polymer. Thus, this argument is non-persuasive in contradicting well known folding dynamics. Applicants then argue that Chen et al. fails to identify a small independently folded subdomain in the target molecule. This is also non-persuasive as each of the elements of such a domain has been noted above as being clearly identified in Chen et al. and thus this argument is non-persuasive as being an allegation which is not supported by the factual evidence in Chen et al. Applicants then argue that Chen et al. has not performed any analysis or experimentation to identify a molecular interaction site as instantly claimed. In response this argument is directed to a limitation which is not in the instant claims and thus non-persuasive in distinguishing the claims over Chen et al. For example, in instant claim 1, line 3, the "identifying at least one molecular interaction site on said target RNA" is set forth. There is no "experimentation" required in said phrase. There is no "analysis" required in said phrase. The choosing of a section of a target RNA is therefore included as a practice within this phrase. Therefore, this

argument also fails to distinguish the instantly claimed invention over Chen et al. Lastly, applicants argue that the determination of a conserved region from different taxonomic species is not disclosed in Chen et al. This is persuasive to overcome the rejection of instant claim 26-28 based on Chen et al. alone.

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 36 (November 15, 1988), 1156 OG 41 (November 16, 1993), and 1167 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to

Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

April 6, 2001

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER